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Case No. N21C-08-216 MMJ

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

LANNETT COMPANY, INC., and SILARX PHARMACEUTICALS, INC.	:	
Plaintiffs,	:	
v.	:	C.A. No. _____ [CCLD]
ZETA PHARMACEUTICALS, LLC,	:	
Defendant.	:	

COMPLAINT

Plaintiffs LANNETT COMPANY, INC. ("**Lannett**") and SILARX PHARMACEUTICALS, INC. ("**Silarx**" and collectively with Lannett "**Plaintiffs**"), by and through their undersigned attorneys, FOX ROTHSCHILD LLP, by way of its complaint against defendant ZETA PHARMACEUTICALS, LLC ("**Zeta**") state as follows:

THE PARTIES

1. Lannett is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 9000 State Road, Philadelphia, PA 19136. Lannett is engaged in the business of manufacturing and distributing generic pharmaceutical products. Silarx is a wholly owned subsidiary of Lannett.

2. Zeta is a corporation duly organized and existing under the laws of the State of New York and maintains its principal place of business at 120 Holmes Avenue, Northeast, Suite 116, Huntsville, Alabama 35801. Upon information and belief, Zeta is engaged in the business of distributing raw materials to the pharmaceutical industry.

Jurisdiction and Venue

3. This Court has personal jurisdiction over Zeta because it expressly consented to personal jurisdiction in Delaware courts through the terms of a purchase order (defined below) related to this action.

4. Venue is proper in this Court because the relevant purchase order (defined below) contains a forum-selection clause requiring that any claim, action, cause of action, proceeding, dispute or other matter arising under or relating to the purchase order be brought only in the courts of the State of Delaware, or the federal court of the United States, located in Delaware.

Factual Background

5. In the United States, the manufacturing and distribution of prescription drug products are regulated, among others, under the Federal Food, Drug and Cosmetic Act, and regulations promulgated and implemented by the United States Food and Drug Administration ("FDA"). Among other things, drug

product manufacturing is subject to strict quality standards to ensure that products are safe and effective for consumption by patients.

6. The raw materials that typically comprise prescription drug products include an "active pharmaceutical ingredient ("API") as well as inactive ingredients. Each and every raw material that is used in the manufacturing of drug products must meet specified purity standards prior to their use in the manufacturing process.

7. Lannett purchases API and inactive ingredients for use in the manufacturing of its drug products from various API suppliers and other chemical manufacturing businesses. Because of the FDA's stringent quality standards, it is very important that Lannett's raw material suppliers provide goods that are free from contaminants, and both patent and latent defects.

8. In order to market and sell a prescription drug product in the United States, a drug company must receive approval from the FDA of either a new drug application ("NDA") or (typically in the case of generic drugs) an abbreviated new drug application ("ANDA").

9. On December 9, 2010, Lannett received approval from the FDA of an ANDA for a generic solution medication known as "Ranitidine Syrup," which was used by patients to treat acid reflux.

10. From time to time, Lannett purchased API from Zeta, including an API known as "Ranitidine HCl," for use in the manufacture of a finished dosage generic drug product known as Ranitidine Syrup, which it sold to customers.

11. Specifically, from the period of November 18, 2015 through September 22, 2018, Lannett issued a series of fifteen (15) purchase orders (the "Purchase Orders") for a total of thirteen thousand two hundred (13,200) kilograms of Ranitidine HCl. Zeta filled the purchase order and delivered the goods to Plaintiffs. Set forth below is a table containing the dates of these orders, deliveries and amounts of product purchased.

Ordered	receipt	purchase order	Batch	Quantity received
12/02/17	04/25/18	4500485400	18228437	750
12/02/17	04/25/18	4500485400	18228438	1,250
02/28/18	10/19/18	4500486514	18235267	1,250
02/28/18	10/19/18	4500486514	18235268	750
09/26/18	05/01/19	4500488596	19241295	1,250
09/26/18	05/01/19	4500488596	19241296	750
11/18/15	11/19/15	4500039288	2015477813	700
12/03/15	01/27/16	4500039571	2016048689	1,000
01/26/16	03/01/16	4500040639	2016099212	250
01/26/16	03/01/16	4500040639	2016099213	250
05/25/16	07/14/16	4500043523	2016281348	1,000
01/20/17	03/15/17	4500048905	2017114553	1,000
01/20/17	03/15/17	4500048905	2017114554	1,000
02/03/17	05/01/17	4500049180	2017185064	1,000
02/03/17	05/01/17	4500049180	2017185065	1,000
			TOTAL	13,200

12. Each of the Purchase Orders provided, among other things, that "[a]ll shipments inbound to Lannett must arrive … free from defects and damage."

13. In each of the Purchase Orders, "[Zeta] represents and warrants that the Goods, Materials … furnished hereunder the Purchase Order to be merchantable within the meaning of the Uniform Commercial Code and fit for their intended purpose."

14. Each of the Purchase Orders also provided that the "Goods, Materials … shall be … free from defects, whether latent or patent, … and shall be suitable for the intended use."

15. Plaintiffs used the goods delivered pursuant to the Purchase Orders to manufacture at least eighty nine (89) batches of Ranitidine Syrup for sale to customers.

16. On or about September 17, 2019, the FDA sent Lannett an Information Request concerning its Ranitidine ANDA. In the Information Request, the FDA notified Lannett that the FDA has learned that N-Nitrosodimethylamine (NDMA) is present in Lannett's competitors' ranitidine drug products as an impurity. According to the FDA Information Request, NDMA is "known to be toxic." FDA requested, among other things, that Lannett provide analysis from at least six finished product batches manufactured with varying API lots for levels of NDMA.

17. In addition, the FDA indicated that if the testing confirmed the presence of detectable amounts of NDMA in the finished product batches, a root cause analysis was to be performed.

18. Finally, the FDA required Lannett to provide to FDA three samples of the finished product for the FDA's own testing.

19. Thereafter, Lannett tested six samples of Ranitidine finished drug product for NDMA and detected NDMA in each of the samples. Lannett undertook a root cause analysis, which included, among other things, the sampling and analysis for the presence of NDMA in three separate lots of API used in the six finished drug product batches which had been sampled. Each of the samples of API tested by Lannett confirmed the presence of NDMA in concentrations that corresponded to those seen in the finished drug product samples. Lannett thus concluded the root cause of the NDMA impurity in the finished drug product was the Ranitidine HCl API delivered by Zeta.

20. On or about October 16, 2019, Lannett provided a response to the FDA Information Request, and provided the results from the analysis of both the samples of Ranitidine finished drug product and API.

21. On or about December 4, 2019, the FDA issued to Lannett a letter entitled "CBE-30 Supplement Request" whereby, among other things, the FDA indicated that it had established 96 ng/day as the maximum daily intake of NDMA.

It requested that Lannett: (1) establish a test method of detecting and measuring NDMA in its finished product; (2) establish a release specification for its Ranitidine Syrup product and Ranitidine HCl API that ensures patient exposure of no more than 96 ng/day; (3) test all finished Ranitidine Syrup before release and distribution, and reject any batch that exceeds 96 ng/day patient exposure to NDMA by its labeled expiration date; and (4) test all previously distributed batches and recall any finished Ranitidine Syrup product from batches which exceed 96 ng/day of patient exposure of NDMA by its labeled expiration date.

22. Additionally, FDA requested that Lannett supplement its Ranitidine Syrup ANDA with a so called "CBE-30" change request to include: (1) submitting a test method for NDMA and full method validation reports; (2) submitting a specification limit for NDMA that does not exceed 96 ng/day; and (3) committing to submit test results and other data relating to the testing of NDMA in the Ranitidine Syrup finished drug product batches and Ranitidine HCl API.

23. By letter dated December 4, 2019, Lannett responded to the FDA CBE-30 Supplement Request and provided the requested information.

24. None of the batches manufactured with the Ranitidine HCl supplied by Zeta met the 96 ng/day limit established by the FDA. As a result, Lannett was required to implement a recall of all distributed Ranitidine Syrup product still in the supply chain.

25. From the Ranitidine HCl supplied by Zeta pursuant to the Purchase Orders, approximately 737,533 bottles of Ranitidine Syrup were manufactured by Silarx. As of the date Lannett committed to a voluntary recall of the Ranitidine Syrup, approximately 54,310 bottles of product manufactured using the API supplied by Zeta remained unsold in in stock at Lannett; the rest were previously distributed to customers.

26. In or about December 2019, Lannett initiated the voluntary recall of all remaining Ranitidine Syrup distributed to its customers by mailing recall packets and follow-up notifications were conducted by Lannett's third party vendor, via telephone calls.

27. Between December 2019 and April 2020, approximately 39,019 bottles of Ranitidine Syrup were returned to Lannett's vendor for destruction pursuant to the recall. The recalled bottles were manufactured and included among fifteen of the eighty nine batches (identified in paragraph 11 above) produced from the API delivered by Zeta. Additionally, approximately 54,310 unsold bottles of Ranitidine Syrup situated in Lannett's facility were unsaleable and required to be destroyed pursuant to the recall.

28. To date, Lannett has incurred in excess of $2.1 million in direct recall expenses arising from the recall of its Ranitidine Syrup containing API pursuant to the Zeta Purchase Orders.

29. All batches of the Ranitidine HCl API provided by Zeta pursuant to the Purchase Orders contained NDMA in amounts in excess of FDA standards. As a direct and proximate result of the Ranitidine API delivered by Zeta pursuant to the Purchase Orders, Lannett has incurred recall expenses in excess of $2.1 million.

COUNT ONE
BREACH OF CONTRACT

30. Plaintiffs hereby repeat and reallege all of the allegations set forth in the preceding paragraphs as if each such allegation was set forth herein at length.

31. The Purchase Orders, subsequently filled by Zeta, constitute binding contracts between Plaintiffs and Zeta.

32. Pursuant to the terms of the Purchase Orders, Zeta, among other things, represented and warranted that the goods delivered shall be merchantable, fit for its intended purpose and free from latent defects.

33. Zeta breached the Purchase Orders and the UCC by providing Ranitidine HCl that was not merchantable or fit for its intended purpose, was not free from latent defects, and was not delivered in accordance with Plaintiffs' specification insofar as the Ranitidine HCl delivered by Zeta contained NDMA contamination in excess of applicable regulatory standards.

34. As a direct and proximate result of Zeta's breach of the Purchase Orders, Plaintiffs have suffered damages, including by not limited to recall

expenses and other damages in excess of $2.1 million, and in an amount to be determined at trial.

WHEREFORE, Plaintiffs demands judgment in its favor and against Zeta in an amount in excess of $2.1 million, with the precise amount to be determined at trial, together with pre- and post-judgment interest, costs, counsel fees and expenses, and such other and further relief the Court deems just and proper consistent with this prayer for relief.

COUNT TWO
NEGLIGENCE

35. Plaintiffs hereby repeat and reallege all of the allegations set forth in the preceding paragraphs as if each such allegation was set forth herein at length.

36. Zeta owed a duty to Plaintiffs to provide manufacturing and delivery of the Ranitidine HCL such that it was free of defects and fit for its intended purpose.

37. Zeta breached its duty to Plaintiffs when it failed to use adequate controls and testing, and failed to manufacture, store and transport the Ranitidine HCl that it delivered to Plaintiffs free from NDMA in amounts in excess of FDA standards.

38. As a direct and proximate result of Zeta's breach of its duties to Plaintiffs, Plaintiffs have incurred recall expenses and other damages in excess of $2.1 million, with the precise amount to be determined at trial, together with pre-

and post-judgment interest, costs, counsel fees and expenses, and such other and further relief as the Court deems just and proper consistent with this prayer for relief.

WHEREFORE, Plaintiffs demand judgment in its favor and against Zeta in an amount in excess of $2.1 million, with the precise amount to be determined at trial, together with pre- and post-judgment interest, costs, counsel fees and expenses, and such other and further relief the Court deems just and proper consistent with this prayer for relief.

COUNT THREE
UNJUST ENRICHMENT

39. Plaintiffs hereby repeat and reallege all of the allegations set forth in the preceding paragraphs as if each such allegation was set forth herein at length.

40. To the extent it is determined that no binding agreement exists between Plaintiffs and Zeta, Plaintiffs assert, in the alternative, a claim for unjust enrichment.

41. Zeta was enriched by the payments made by Plaintiffs for the goods delivered by Zeta.

42. Plaintiffs lost the value of the payments made to Zeta for those good because the goods delivered by Zeta were defective.

43. Zeta was required to provide goods without defects to Plantiffs and was not justified in retaining the value of the payments made by Lannett when it delivered defective goods.

44. As a direct and proximate result of Zeta's retention of the payments made by Lannett for defective goods, Zeta was unjustly enriched by the payments it received from Plaintiffs.

WHEREFORE, Plaintiffs demand judgment in its favor and against Zeta in an amount to be determined at trial, together with pre- and post-judgment interest, costs, counsel fees and expenses, and such other and further relief the Court deems just and proper consistent with this prayer for relief.

FOX ROTHSCHILD LLP

By: */s/ Seth A. Niederman*

Seth A. Niederman, Esquire (No. 4588)
Kasey H. DeSantis, Esquire (No. 5882)
919 North Market Street, Suite 300
Wilmington, DE 19899-2323
Phone (302) 654-7444/Fax (302) 656-8920
sniederman@foxrothschild.com
kdesantis@foxrothschild.com

-and-

William Stassen, Esquire
2000 Market Street, Twentieth Floor
Philadelphia, PA 19103-3232
Phone (215) 299-2000/ Fax (215) 299-2150
wstassen@foxrothschild.com

Dated: August 25, 2021

Attorney for Plaintiffs Lannett Company, Inc. and Silarx Pharmaceuticals, Inc.